

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

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OFFICE OF

## MEMORANDUM

SUBJECT: Request For Modification To Wood Preservative

Consumer Information Sheet

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TO: Spencer L. Duffy

Special Review Division

Office of Pesticide Programs (H-7508C)

On July 10, 1989, Frederick H. von Unwerth, Attorney for Hickson Corporation, requested that the Agency agree to a modification of the Consumer Information Sheet for WOLMANIZED pressure-treated wood (a chromated copper arsenate product) to allow the use of such wood in the construction of water troughs and feed and silage bunkers for food-producing animals. Consumer Information Sheet (CIS) is part of a Consumer Awareness Program which has been voluntarily undertaken by the wood preserving industry as part of a Settlement Agreement in the Special Review of the wood preservative pesticides. Settlement Agreement permits modifications to the agreed-upon CIS language with the approval of EPA and the other signatories to the Agreement. Currently, the CIS for arsenical treated wood does not permit the use of treated wood "under circumstances where the preservatives may become a component of food or animal feed", and specifically gives as an example of a prohibited use "structures or containers for storing silage or food." 51 Fed: Reg. 1334, 1347 (January 10, 1986).

In accordance with a 1971 memorandum of understanding, FDA has the responsibility for establishing food additive regulations for wood preservative pesticides that are added to food contact materials since the purpose of the preservative is to protect the wood rather than the food. Hickson, the manufacturer of WOLMANIZED pressure-treated wood, submitted a request to FDA to allow the use of WOLMANIZED pressure-treated wood in the construction of silage and feed bunkers, as well as water troughs for food producing animals. This request was accompanied by leaching data. On February 23, 1989, the Director of the

Division of Animal Feeds, Center for Veterinary Medicine, FDA informed Hickson that FDA does "not object to the marketing of 'WOLMANIZED' wood" for the requested purposes. Accordingly, Hickson has now requested the Agency to modify the CIS to allow these uses. In support of its request, Hickson provided the data which had been submitted to FDA.

Since the Settlement Agreement provided that no modifications could be made to the CIS without the approval of the Agency and the other signatories to the Agreement, FDA's "approval" is not dispositive. Rather, the Agency has the authority under the terms of the Settlement Agreement to independently determine if the modification is appropriate, even though FDA in fact has the authority to set food additive regulations for the use of the wood preservatives in food contact materials. Thus, the Agency must independently review the data to determine if such data warrants a change to the CIS.

The data was, in fact, submitted to the Dietary Exposure Branch of the Health Effect Division of the Office of Pesticide Programs for review. In a review dated September 26, 1989, Francis B. Suhre, Chemist, concluded that "(t)he residue data submitted with this action do not satisfy the requirements of 40 CFR 158.240." He recommended that "the discrepancy resulting from FDA's authorization of food/feed uses of Wolmanized Pressure Treated-Lumber, and EPA's restriction against the same use be resolved." This bare conclusion does not provide sufficient information to determine if the data submitted by Hickson is adequate to warrant a change in the CIS.

To resolve the issue of whether or not the CIS should be changed, the data review must determine what the data shows about the leachability of the CCA in the wood. The fact that the data does not satisfy EPA's guidelines is not necessarily dispositive. Since there is no discussion of the data in the September 26, 1989 review, and no evaluation of what this data shows, it is not possible to reach any regulatory conclusions about the CIS

It is noteworthy that the FDA "approval" was in the form of a letter "not objecting" to the use, rather than by formal rulemaking. This form of approval would appear to be highly unusual, since the statutory scheme provides that a food containing residues of a food additive is adulterated unless there is a food additive regulation covering such residues. In the absence of such a regulation, the presence of arsenic residues in the food would technically render the food adulterated. Practically, of course, unless the arsenic were present at levels above normal background, adulteration would not be found. Apparently what FDA is saying is that, in their opinion, any arsenic residues from the uses in question would not result in residues above background levels.

language. Basically, what is necessary for a regulatory conclusion here is a standard chemistry review which summarizes the data, provides an evaluation of the quality of the data, and a conclusion as to what the data shows. The toxicologists must then determine if the residues which are present on the food pose a health risk. Only with such information can the Agency determine the appropriate response to the request for modification of the CIS.